Generic Reliability Plan

Set Goals: Benchmark competition – allocate reliability goal to subassemblies, key components

Risk Management: Identify hazards & risks, put risk control measures into requirements spec.

Wear-Out Failures: (right end of the bathtub curve)

Estimate Worst Case Usage:
For each part that receives cyclical stress (mechanical parts that rub, flex, or rotate; electrical parts that take surges of voltage, current, or power), estimate the number of cycles that the 99.9%ile user will put on the part in the expected lifetime of the device. Generate a table of such cycles. See Appendix A for examples of how to do this.

Risked-Based Requirements:
Based on the Severity of the Harm that could result from failure of the part from Risk Management, verify that the 99.9%ile usage will be met with the following reliability. This is at 50% statistical confidence, see Appendix B for explanation.

Severity	Negligible	Marginal	Critical	Catastrophic
Reliability	0.841	0.900	0.950	0.990

Severity Definitions:
- Catastrophic is death or serious injury (loss of function, organ, limb)
- Critical is injury requiring medical intervention to prevent serious injury
- Marginal is injury not requiring medical intervention from which full recovery is expected
- Negligible is irritation, annoyance, or minor injury with immediate recovery

This verification may be done by citing manufacturer's test data if the proposed application in the device is less stressful than the manufacturer's test situation. If the manufacturer's test is not as stressful, additional testing must be done.

Plan the sample size and cycles to verify the above reliability. Weibull beta of 2 may be assumed for test planning purposes, however if failures occur, a new beta must be deduced from the data points.

Useful-Life (random-in-time) Failures: (middle of the bathtub curve)

Useful Life Reliability (low warranty failure rate) is obtained by having Design Margin beyond the required limits of use. This means a small quantity (4 to 8 devices) should be run sufficiently beyond specifications to ensure there are no marginal component applications. Typical stresses are: Temperature, Vibration, Humidity, Supply Voltage, Clock Frequency, Power Cycling, etc. These stresses should be run individually and then in combination.

Sufficiently beyond specification is for example: +25% and -50% on Clock Frequency, 30 degrees Celsius beyond specification, 4 to 6 volts on a 5V supply, and so on. Except for humidity, these stresses can be conveniently applied simultaneously using HALT (Highly Accelerated Life Test) equipment. HALT and fixing the discovered issue pushes out and establishes new Operating Limits and Destructive Limits. These limits are used to design manufacturing screening regimens.

Plan the overstress testing and / or HALT including what stresses and limits are intended to ensure all components have sufficient design margin.

Early-Life (infant mortality) Failures: (Beginning of the bathtub curve)

Caused by manufacturing anomalies or damage in shipping, storage, and / or handling, components are wounded in such a way that they contain stress concentrators. These latent (hidden) defects will test good, but fail early (first 90-days) in the product's life. Latent defects must be Precipitated (made patent or visible to test) by exposure to stress. The stress concentrator will cause preferential failure of the wounded part compared to typical parts. Hence latent defects can be eliminated before shipping the device.

Run-in, Burn-in, Environmental Stress Screening (ESS), and Highly Accelerated Stress Screening (HASS) are all methods of Precipitating these defects which must then be Detected. A Proof of Screen is run to ensure the trial regimen is tough enough to Precipitate defects, but not so tough as to use up too much Fatigue Life (Safety of Screen ensures this).

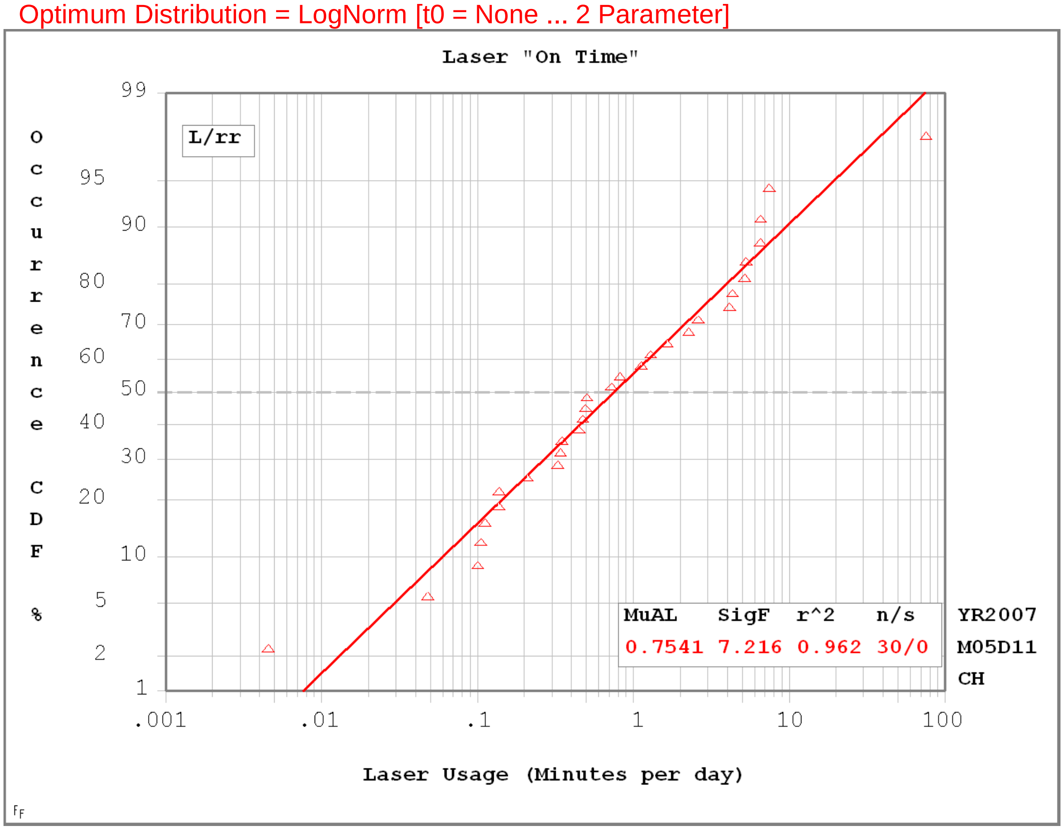
Plan for manufacturing screening to eliminate Early-Life failures. Include the plan for Proof of Screen, including number of times through the trial regimen to show Safety of Screen.

Appendix A Deriving the 99.9 Percentile Requirement

Example 1:

Internal logs from products returned for service are automatically downloaded into a database. Among other things, the database shows how many minutes the laser has been run. A quality engineer manipulates the database to compute minutes per day of laser "on time" by subtracting the installation date from the return date, allowing 3 days for shipping delays, and dividing this age in days into the total minutes the laser has been run for each unit. This distribution is plotted on a statistical program that tries to fit a variety of distributions to the data and selects the one with the best fit. The 99.9 percentile value is read from the program.

Life Data Distribution Analysis (Regression)
W:Weibull [t0 = None ... 2 Parameter]
W: Correlation(r)=.97005 r^2=.941 ccc^2=.9222 r^2-ccc^2=.0188 (Okay)
W: Characteristic Value=1.796 Weibull Slope=.6374 Method=rr
3:Weibull [t0 = 1.655263E-03 ... 3 Parameter] [Scale Not As Recorded]
3: Correlation(r)=.97108 r^2=.943 ccc^2=.9627 r^2-ccc^2=-.0197 (r^2<ccc^2!)
3: Characteristic Value=1.798 Weibull Slope=.6219 Method=rr/t0^
L:LogNorm [t0 = None ... 2 Parameter]
L: Correlation(r)=.98082 r^2=.962 ccc^2=.9383 r^2-ccc^2=.0237 (Okay)
L: Log-Mean Antilog=.7541 Std. Dev. Factor=7.216 Method=rr
Optimum Distribution = LogNorm [t0 = None ... 2 Parameter]



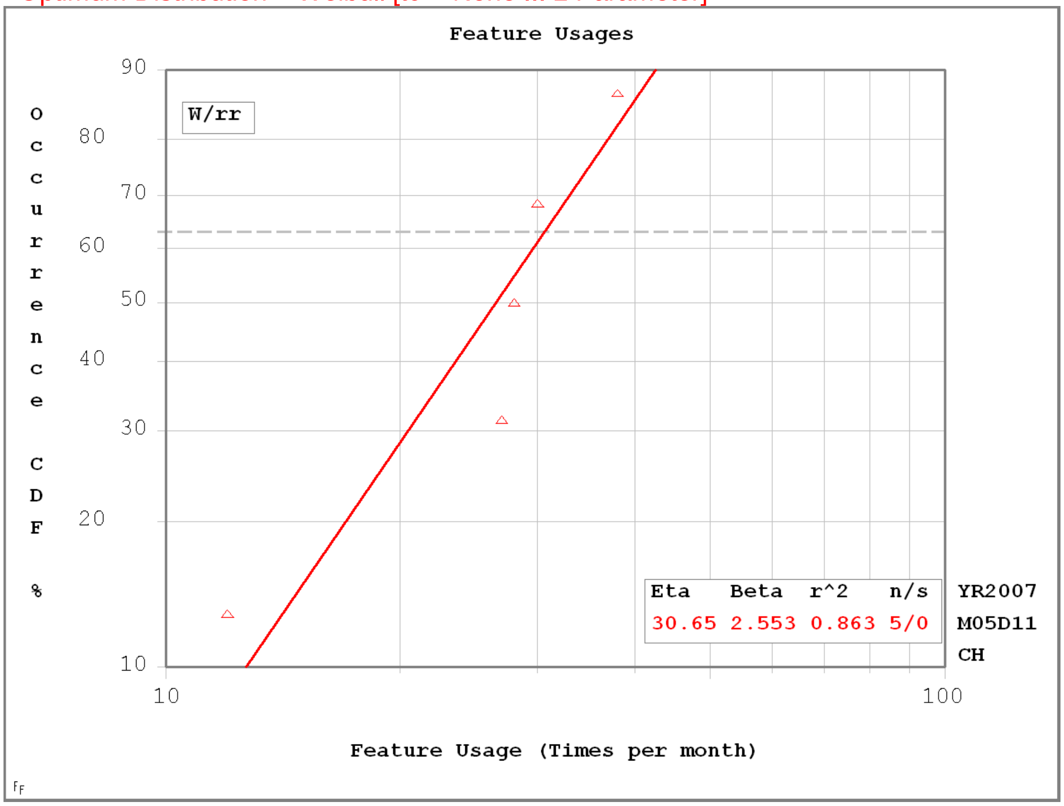
Set 1 - ... SigF = 7.216251 MuAL = .7540545
At Laser Usage = 338.521 (Minutes per day) (Z-Value = 3.09)
.998999999985099 (99.9%) Will Occur (Will Be <)
1.00000001490119E-03 (.1%) Will NOT Occur (Will Be >)

The 99.9 percentile usage will be taken to be 339 minutes per day for new designs.

Example 2:

Five "thought leaders" are asked how frequently they would use a particular feature on a medical device if it were available. They were asked to express their answers in times per month to include the effect of clinic hours (some were open on Saturday). Their answers were 38, 27, 30, 12, and 28 times per month.

Life Data Distribution Analysis (Regression)
(Caution: Occurrence Quantity < 20 ... 2-Parameter Weibull = Standard)
W:Weibull [t0 = None ... 2 Parameter]
W: Correlation(r)=.92898 r^2=.863 ccc^2=.8064 r^2-ccc^2=.0566 (Okay)
W: Characteristic Value=30.65 Weibull Slope=2.553 Method=rr
3:Weibull [t0 =-5725.501 ... 3 Parameter] [Scale Not As Recorded]
3: Correlation(r)=.95864 r^2=.919 ccc^2=.893 r^2-ccc^2=.026 (Okay)
3: Characteristic Value=5757 Weibull Slope=659.4 Method=rr/t0^
L:LogNorm [t0 = None ... 2 Parameter]
L: Correlation(r)=.88994 r^2=.792 ccc^2=.8136 r^2-ccc^2=-.0216 (r^2<ccc^2!)
L: Log-Mean Antilog=25.29 Std. Dev. Factor=1.567 Method=rr
Optimum Distribution = Weibull [t0 = None ... 2 Parameter]



Set 1 - ... Beta = 2.552924 Eta = 30.64993
At Feature Usage = 65.34383 (Times per month) (Y-Value = 1.932647)
.998999999985099 (99.9%) Will Occur (Will Be <)
1.00000001490119E-03 (.1%) Will NOT Occur (Will Be >)

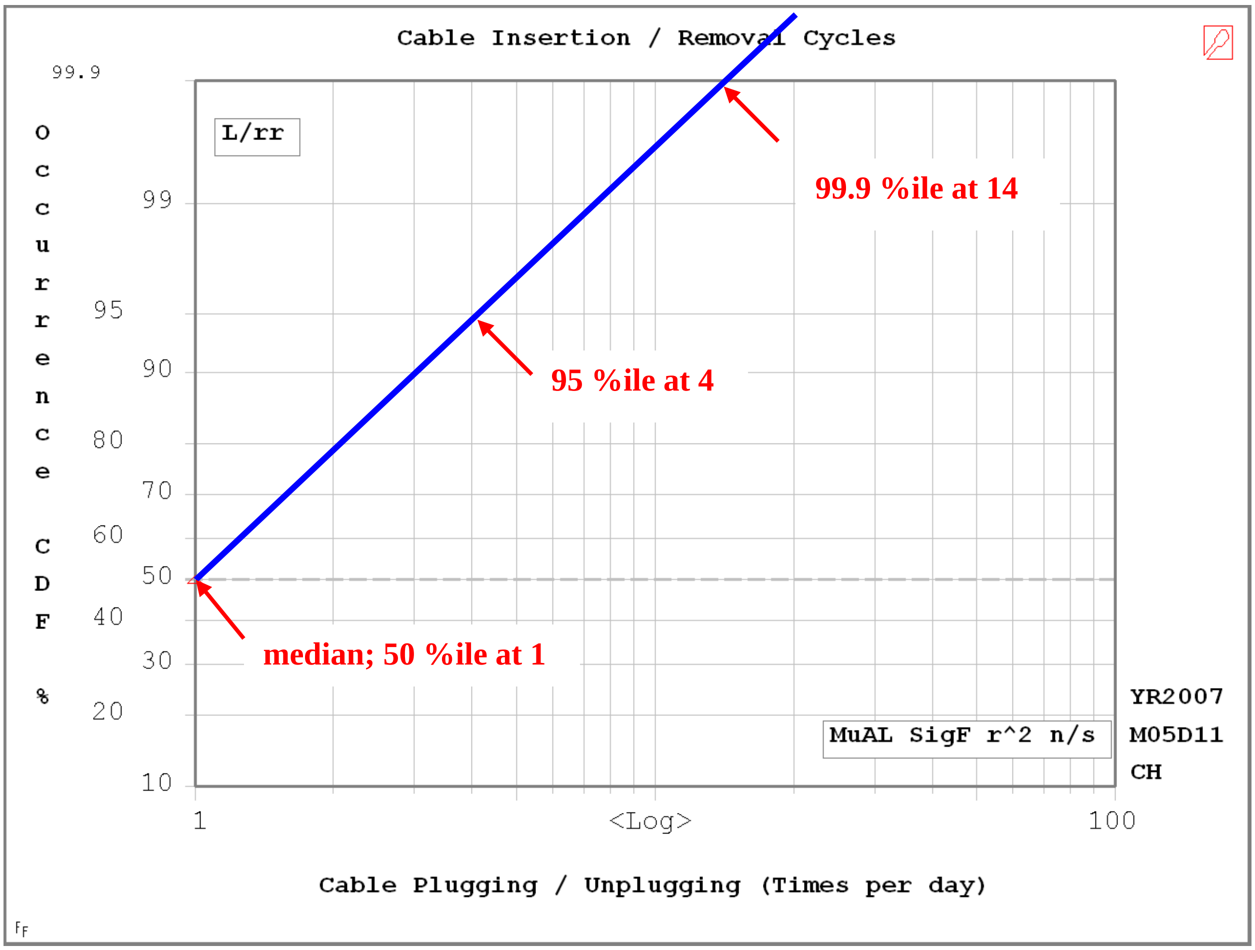
The 99.9 percentile usage will be taken to be 66 times per month for new designs.

Example 3

A clinical specialist states that typically this cable gets unplugged once a day when the room is wiped down, but in some cases every time the equipment is used, which could be 4 times a day.

The quality engineer reasons that since the number of insertions and removals can't be a negative number, a Normal distribution doesn't make sense, but a Lognormal might be appropriate. She also figures the clinical specialist is talking the 95 percentile case for the upper number.

She prints out a sheet of graph paper for Lognormal and manually adds the two points and extrapolates to the 99.9 percentile point.



The 99.9 percentile usage will be taken as 14 insertions and removals per day.

The connector will be specified and tested to typically survive to 10,220 insertion / removal cycles in its specified two-year life.

Appendix B: Statistical Confidence in Setting and Verifying Requirements

Throughout this Reliability Plan, 50% statistical confidence is used. This is equivalent to using an arbitrary confidence.

The advantages of using 50% statistical confidence are:

1. Graphs are less cluttered and simpler to understand.
2. 50% confidence is the best estimate of the actual value.
3. Requirements are simpler to understand without confidence.
4. 50% confidence is independent of the method of computing confidence.
5. When reliabilities are combined, the 50% confidence values simply multiply.

Attribute data is demonstrated by testing a certain quantity of product, typically with 0 failures for the shortest test or smallest sample size. The formula for 0 failures (derived from the first term of the binomial expansion) is:

$$R^n = 1\text{-}C$$

Where **R** is reliability (fraction conforming), **n** is the number of samples (prototypes) tested, and **C** is the statistical confidence. "Reliability raised to the nth power equals one minus the Confidence."

When one tests a number of samples without failure, one is simultaneously demonstrating an infinite number of different reliabilities, each at a different statistical confidence. A typical example is demonstrating 0.95 reliability (fraction conforming) at 95% statistical confidence. The formula says to test 59 units.

59 units with 0 failures is:

Statistical Confidence	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%
Reliability	0.95049	0.96172	0.96836	0.97309	0.97678	0.97980	0.98236	0.98459	0.98656	0.98832

There is nothing more or less valid about any of these sets of reliability and confidence; they are equivalent.

Variable data is demonstrated by testing a sample, say 10 units, fitting a distribution to the data pints and then (typically) extrapolating to the required limit (e.g. force, voltage, torque) and reading the reliability (fraction conforming) at the requested statistical confidence.

For example, the following data was taken from an Instron Tensile Tester on force to remove a connector:

Force	5.29	4.57	4.83	5.99	5.31	4.84	4.91	5.18	4.62	4.21

The requirement is for less than 7 pounds with at least 0.99 reliability (fraction conforming) at 95% statistical confidence.

Several distributions were fit to the data with the best fit being a Lognormal. The 95% single-sided upper confidence bound is computed using the Fisher Matrix method. Different methods of computing confidence would result in different values for the force with 0.99 reliability at 95% confidence.

Again an infinite number of reliabilities each at a different confidence can be presented from these data.

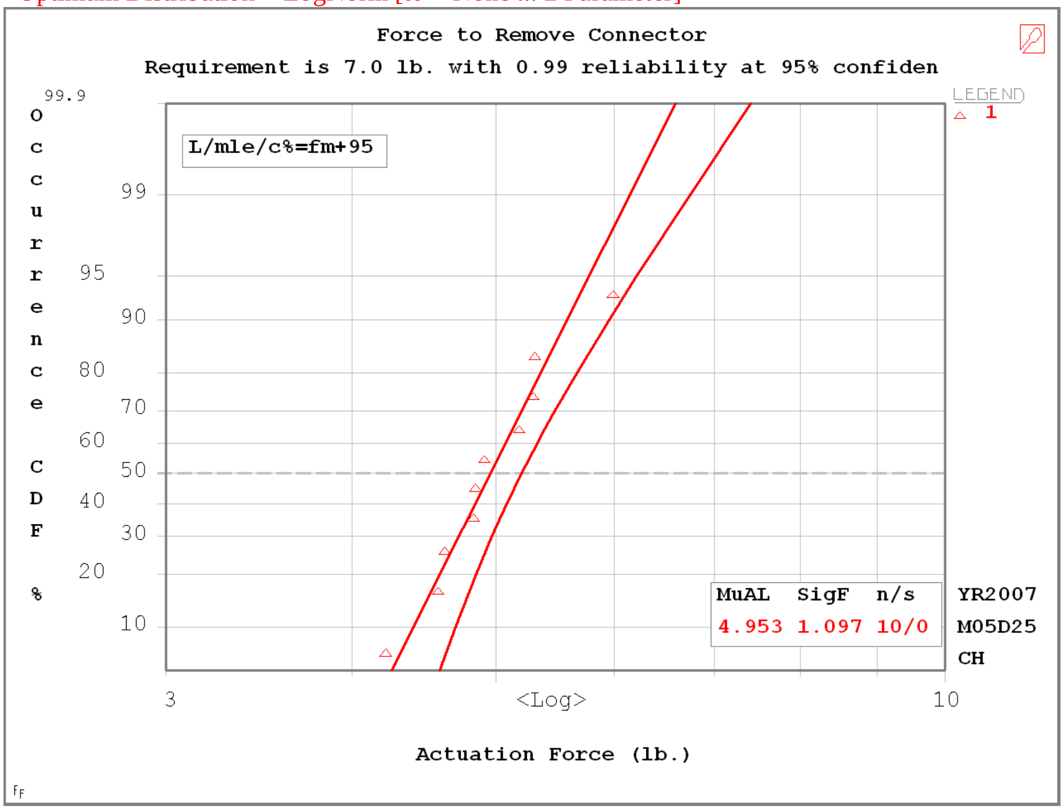
Statistical Confidence	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%
Reliability	0.99573	0.99763	0.99850	0.99900	0.99932	0.99953	0.99968	0.99978	0.99985	0.99990

There is nothing more or less valid about any of these sets of reliability and confidence; they are equivalent.

The fit information, graph, and result is presented on the following two pages with and without using confidence.

Force to Remove Connector

Life Data Distribution Analysis (Likelihood)
W:Weibull [t0 = None ... 2 Parameter]
W: Log Likelihood (LL)= -7.537253
W: Characteristic Value=5.195 Weibull Slope=10.42 Method=mle
3:Weibull [t0 = 3.703365 ... 3 Parameter] [Scale Not As Recorded]
3: Log Likelihood (LL)= -6.651657
3: Characteristic Value=1.348 Weibull Slope=3 Method=mle/t0^
L:LogNorm [t0 = None ... 2 Parameter]
L: Log Likelihood (LL)= -6.411047
L: Log-Mean Antilog=4.953 Std. Dev. Factor=1.097 Method=mle
2 Parameter Optimum Distribution: LogNorm [t0 = None ... 2 Parameter]
LR Test: Weibull 3 Parameter - LogNorm < 50 % Significance
Optimum Distribution = LogNorm [t0 = None ... 2 Parameter]



Set 1 - 1 ... SigF = 1.097198 MuAL = 4.952575
At Actuation Force = 6.743379 (lb.)
 > .99 (99%) Will Occur
 < 9.99999E-03 (1%) Will NOT Occur
[Confidence = 95%]

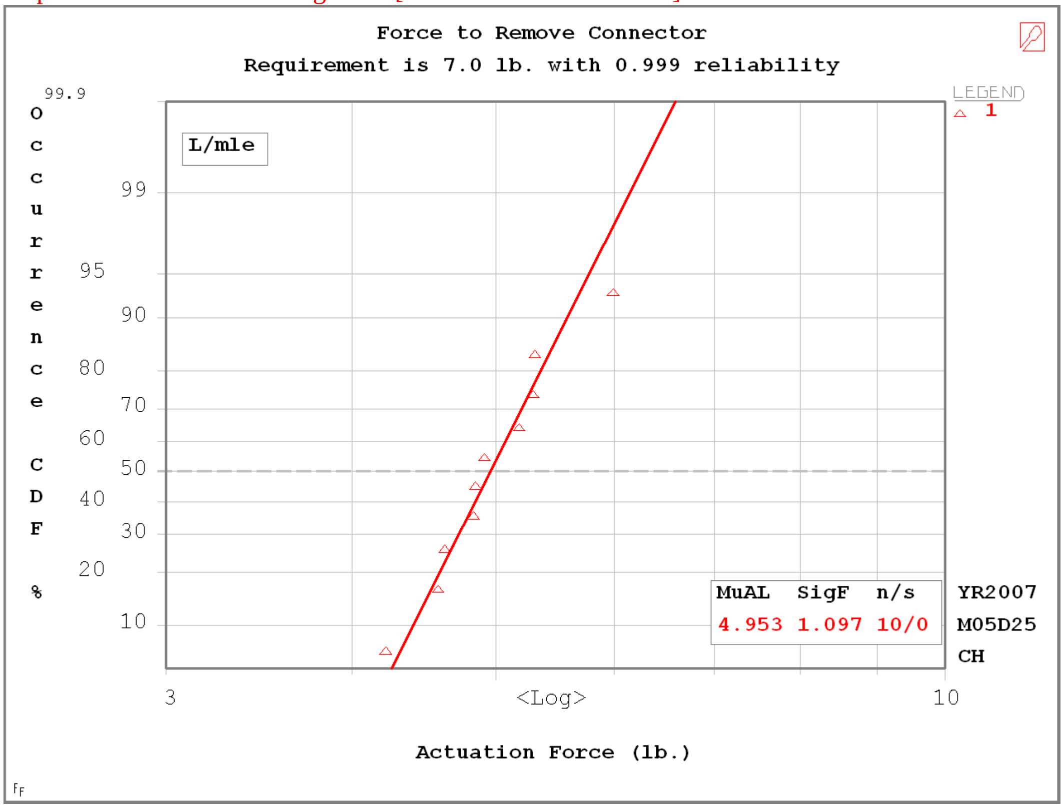
The force is 6.7 lb. with 0.99 reliability at 95% statistical confidence.

Set 1 - 1 ... SigF = 1.097198 MuAL = 4.952575
At Actuation Force = 7 (lb.)
 > .9957258 (99.57%) Will Occur
 < 4.274249E-03 (.43%) Will NOT Occur
[Confidence = 95%]

The reliability at 7.0 lb. is 0.99573 at 95% statistical confidence.

Force to Remove Connector

Life Data Distribution Analysis (Likelihood)
W:Weibull [t0 = None ... 2 Parameter]
W: Log Likelihood (LL)= -7.537253
W: Characteristic Value=5.195 Weibull Slope=10.42 Method=mle
3:Weibull [t0 = 3.703365 ... 3 Parameter] [Scale Not As Recorded]
3: Log Likelihood (LL)= -6.651657
3: Characteristic Value=1.348 Weibull Slope=3 Method=mle/t0^
L:LogNorm [t0 = None ... 2 Parameter]
L: Log Likelihood (LL)= -6.411047
L: Log-Mean Antilog=4.953 Std. Dev. Factor=1.097 Method=mle
2 Parameter Optimum Distribution: LogNorm [t0 = None ... 2 Parameter]
LR Test: Weibull 3 Parameter - LogNorm < 50 % Significance
Optimum Distribution = LogNorm [t0 = None ... 2 Parameter]



Set 1 - 1 ... SigF = 1.097198 MuAL = 4.952575
At Actuation Force = 6.596476 (lb.) (Z-Value = 3.09)
.999000015258789 (99.9%) Will Occur (Will Be <)
9.99984741210991E-04 (.1%) Will NOT Occur (Will Be >)
[Confidence = 50%]

The force is 6.6 lb. with 0.9990 reliability.

Set 1 - 1 ... SigF = 1.097198 MuAL = 4.952575
At Actuation Force = 7 (lb.) (Z-Value = 3.730088)
.999904274940491 (99.99043%) Will Occur (Will Be <)
9.57250595092773E-05 (9.572506E-03%) Will NOT Occur (Will Be >)
[Confidence = 50%]

The reliability at 7.0 lb. is 0.9999.